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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiffs, v. **Lannett Company, Inc., Impax Laboratories, Inc., West-Ward Pharmaceuticals Corporation, Allergan plc; Mylan Pharmaceuticals, Inc., and Par Pharmaceutical Companies, Inc.** Defendants.	**CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL** **No:** 16 2468

INTRODUCTION

1. Plaintiff Philadelphia Federation of Teachers Health and Welfare Fund, ("PFTHW" or "Plaintiff") brings this action both individually and on behalf of:

a. a national injunctive class of persons or entities in the United States and its territories who purchased, paid and/or provided reimbursement for some or all of the purchase price of generic digoxin or doxycycline products manufactured by Defendants during the period from October 1, 2012 to the present; and

b. a damage class of persons or entities in the purchased, paid and/or provided reimbursement for some or all of the purchase price of generic digoxin or doxycycline products manufactured by Defendants during the period from October 1, 2012 to the present in the 30 states identified herein and the District of Columbia. Defendants are accused of engaging in a conspiracy to fix, maintain, and/or stabilize the prices of these generic drug products. All allegations herein are based on information and belief, except for those relating to the Plaintiff.

2. The claims in this case arise from a broad conspiracy among manufacturers of generic drugs to fix the prices charged for those drugs in recent years. The conspiracy appears to have been effectuated by direct company-to-company contacts among generic drug manufacturers, as well as joint activities undertaken through trade associations such as the Generic Pharmaceutical Association ("GPHA"). The unlawful acts undertaken with respect to generic digoxin and doxycycline are merely two manifestations of that overall conspiracy. The Antitrust Division of the United States Department of Justice ("DOJ") commenced in 2014 a wide-ranging criminal investigation of this broad conspiracy and has caused grand jury subpoenas to be issued to various Defendants in connection with this investigation. The investigation encompasses generic drugs other than digoxin and doxycycline and, as the scope of the DOJ's investigation is further clarified, Plaintiff reserves the right to amend its complaint to add more parties and/or claims. According to a June 26, 2015 report by the service Policy and Regulatory Report ("PaRR Report") (available at http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf):

A PaRR source says prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department's largest criminal antitrust probe ever. Like in that case, prosecutors expect "to move from one drug to another in a similar cascading fashion."

3. The entire purpose of permitting a generic drug industry in the United States was to encourage the manufacture of less expensive, non-branded substitutes for branded prescription drugs that either had no patent exclusivity or for which the patent exclusivity was expiring. According to a March 12, 2015 PowerPoint presentation by Defendant

Lannett ("Lannett 2015 Presentation"), eight out of ten prescriptions are filled for generic drugs. According to that presentation, this is because the United States healthcare system focuses on "cost saving", thereby "increasing demand for cheaper generic drugs."[1] In a January 2012 report, the Government Accounting Office noted that "[o]n average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug."[2]

4. As reflected in a chart compiled by Representative Elijah E. Cummings ("Cummings"), Ranking Member of the House Committee on Oversight and Government Reform and Senator Bernie Sanders ("Sanders"), Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions, prices for certain generic drugs, including digoxin and doxycycline, increased dramatically in 2013:[3]

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[1] https://www.business.illinois.edu/finance/rcmp/research/LCI2015-3.pptx.
[2] http://www.gao.gov/assets/590/588064.pdf.
[3] http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price- increases?inline=file.

Drug	Use	Average Market Price Oct. 2013	Average Market Price April 2014	Average Percentage Increase
Doxycycline Hyclate (bottle of 500, 100 mg tablets)	antibiotic used to treat a variety of infections	$20	$1,849	8,281%
Albuterol Sulfate (bottle of 100, 2 mg tablets)	used to treat asthma and other lung conditions	$11	$434	4,014%
Glycopyrrolate (box of 10 0.2 mg/mL, 20 mL vials)	used to prevent irregular heartbeats during surgery	$65	$1,277	2,728%
Divalproex Sodium ER (bottle of 80, 500 mg tablets ER 24H)	used to prevent migraines and treat certain types of seizures	$31	$234	736%
Pravastatin Sodium (bottle of 500, 10 mg tablets)	used to treat high cholesterol and to prevent heart disease	$27	$196	573%
Neostigmine Methylsulfate (box of 10 1:1000 vials)	used in anesthesia to reverse the effects of some muscle relaxants	$25	$121	522%
Benazepril/Hydrochlorothiazide (bottle of 100, 20-25 mg tablets)	used to treat high blood pressure	$34	$149	420%
Drug	**Use**	**Average Market Price Nov. 2012**	**Average Market Price Sept. 2014**	**Average Percentage Increase**
Isuprel (box of 25, 0.2 mg/mL vials)	used to treat heart attacks and irregular heartbeat	$916	$4,489	390%
Nitropress (50 mg vial)	used to treat congestive heart failure and reduce blood pressure	$44	$215	388%
Drug	**Use**	**Average Market Price Oct. 2012**	**Average Market Price June 2014**	**Average Percentage Increase**
Digoxin (single tablet, 250 mcg)	used to treat irregular heartbeats and heart failure	$0.11	$1.10	884%

5. Digoxin is used to treat mild to moderate heart failure in adults, increase the heart contracting functions for pediatric patients with heart failure, and control the resting heart rate in adult patients with chronic atrial fibrillation.[4] It is derived from the leaves of a digitalis (or foxglove) plant and was first described in medical literature around 1785. Digoxin helps an injured or weakened heart pump blood more efficiently and strengthens the force of the heart muscle, which helps to restore a normal, steady heart rhythm. It is on the World Health Organization's ("WHO") list of essential medicines.[5] Digoxin must be taken daily and exactly as prescribed to be effective. Failure to take digoxin as

[4] As used herein, the term "digoxin" is intended to refer to doses of digoxin taken orally in the form of a tablet or capsule.

[5] *See* http://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_AUG2015.pdf?ua=1.

prescribed can have catastrophic consequences. According to data from IMS Health, annual sales of digoxin in the United States are approximately $44 million as of the beginning of 2014. As indicated in the discussion below, those sales numbers increased dramatically in 2014 and 2015.

6. Doxycycline monohydrate is an antibiotic used in treating humans and animals. It is useful for bacterial pneumonia, acne, chlamydia infections, *Clostridium difficile* colitis, early Lyme disease, cholera and syphilis. It is also useful for the treatment of malaria when used with quinine and for the prevention of malaria. It came into use in 1967 and is also on WHO's list of essential medicines referenced above. Doxycycline hyclate is a variation of doxycycline monohydrate that entered the market in 1985. As used herein, the term "doxycycline" refers to both doxycycline monohydrate and doxycycline hyclate in tablet or capsule form, unless otherwise indicated.

7. The price increases described above endanger human lives. Many patients with cardiovascular conditions need to take digoxin daily in order to survive. Likewise, people with serious infections or other life-threatening diseases need access to a ready, affordable supply of doxycycline. Many have limited ability to cope with these types of price hikes.

8. Defendants, Lannett Company, Inc. ("Lannett"), Impax Laboratories, Inc. ("Impax"), West-Ward Pharmaceuticals Corp. ("West-Ward"), Mylan Pharmaceuticals, Inc. ("Mylan"), and Par Pharmaceutical Companies, Inc. ("Par"), are manufacturers and/or distributors of generic digoxin. These Defendants collectively sell tens of millions of dollars' worth of digoxin every year in the United States. Lannett, West-Ward, Par and Mylan are also manufacturers of generic doxycycline. Another major supplier of generic

doxycycline has been the Actavis unit of Defendant Allergan plc.[6] On March 17, 2015, Actavis plc ("Actavis") completed its acquisition of Allergan, Inc. in a cash and equity transaction valued at approximately $70.5 billion. As part of the transaction, Actavis plc changed its name to Allergan plc ("Allergan"), the entity named as a Defendant herein.

9. The markets for generic digoxin and generic doxycycline are oligopolies. Thus, in the generic digoxin market, mergers and withdrawals from the market caused the number of competitors to shrink drastically. By October 2013, the generic digoxin market was essentially a duopoly controlled by Lannett and Impax. Defendant West-Ward, a subsidiary of Hikma Pharmaceuticals PLC ("Hikma"), is also a competitor, but it had to suspend operations in November of 2012 in the wake of an investigation by the United States Food & Drug Administration ("FDA") into production problems at its manufacturing facility. It resumed participation in the generic digoxin market in July 2013. Mylan and Par entered that market in 2014 and 2015, respectively. Arthur Bedrosian ("Bedrosian"), the CEO of Lannett, calls these companies "rational" competitors. Similarly, Par, West-Ward, Mylan, Allergan and Lannett are also major players in the market for generic doxycycline.

10. Defendants' dramatic and unexplained price hikes have engendered extensive scrutiny by the United States Congress and by federal and state antitrust regulators. In a January 8, 2014, letter to members of key committees of the United States House of Representatives and Senate, Douglas P. Hoey, Chief Executive Officer of the

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[6] http://www.allergan.com/Actavis/media/PDFDocuments/2013_US_Rx_Product_Catalog.pdf. The predecessor to Actavis plc also manufactured a generic form of digoxin at plants in New Jersey, but in December of 2008, it agreed to cease doing so after the DOJ sued it for violating the FDA's manufacturing regulations. *See* http://www.law360.com/articles/81363/correction- actavis-to-halt-production-at-3-plants. The company no longer sells generic digoxin in the United States.

National Community Pharmacists' Association, asked Congress to conduct an investigation of generic drug price increases.[7] On October 2, 2014, Sanders and Cummings sent letters to Actavis, Lannett, Impax, Mylan, and West-Ward ("October Letters") asking for detailed information on the generic digoxin and/or generic doxycycline hyclate price hikes, among others.[8]

11. On November 20, 2014, Sanders's committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?" ("Senate Hearing"). Various witnesses discussed the price hikes for generic drugs. Although Bedrosian, the CEO of Lannett, was invited to testify, neither he nor any other chief executive of a generic drug manufacturer did so.[9]

12. Industry analysts have also questioned manufacturers' claims that price increases are due to supply disruptions. Indeed, Richard Evans at Sector & Sovereign Research recently wrote: "[a] plausible explanation [for price increases of generic drugs, including generic digoxin] is that generic manufacturers, having fallen to near historic low levels of financial performance are cooperating to raise the prices of products whose characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation."[10]

13. Antitrust regulators have also been actively investigating the price hikes. In August 2014, the Connecticut Attorney General ("AG") opened an antitrust investigation into digoxin pricing. Lannett, Impax and Par were subpoenaed concerning a conspiracy to

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[7] https://www.ncpanet.org/pdf/leg/jan14/letter-generic-spikes.pdf.
[8] The October Letters may be found at http://www.sanders.senate.gov/newsroom/press- releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.
[9] http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes.
[10] http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-a- slowdown-coming.

restrain trade by fixing the price of digoxin or allocating and dividing customers or territories. A copy of the subpoena issued to Lannett is attached hereto as Exhibit "A" and confirms that digoxin pricing is at the heart of the investigation. Par reported that it completed its "response" to the Connecticut AG on October 28, 2014.

14. By November 3, 2014, as noted above, the DOJ opened a criminal grand jury investigation into the pricing of various generic drugs, including generic digoxin and generic doxycycline. To date, according to statements in public filings with the Securities & Exchange Commission ("SEC") discussed below, the grand jury has issued subpoenas to Lannett and Lannett's Vice-President of Sales and Marketing (believed to be Kevin Smith ("Smith"), according to Lannett's website (http://www.lannett.com/about-lannett-management.php)); Impax and an unidentified sales representative of Impax; Allergan; Par; and Mylan.

15. Plaintiff alleges that during the Class Period, Defendants conspired, combined and contracted to fix, raise, maintain and stabilize prices at which generic digoxin and generic doxycycline would be sold. As a result of Defendants' unlawful conduct, Plaintiff and the other members of the proposed Classes paid artificially inflated prices that exceeded the amount they would have paid if a competitive market had determined prices for generic digoxin and generic doxycycline.

JURISDICTION AND VENUE

16. Plaintiff brings this action under Section 16 of the Clayton Act (15 U.S.C. § 26), for injunctive relief and costs of suit, including reasonable attorneys' fees, against Defendants for the injuries sustained by Plaintiff and the members of the Class by reason of the violations of Sections 1 and 3 of the Sherman Act (15 U.S.C. § 1, 3).

17. This action is also instituted under the antitrust, consumer protection, and common laws of various states for damages and equitable relief, as described in Counts Two through Four below.

18. Jurisdiction is conferred upon this Court by 28 U.S.C. §§1331 and 1337 and by Section 16 of the Clayton Act (15 U.S.C. §26). In addition, jurisdiction is also conferred upon this Court by 28 U.S.C. §1367.

19. Venue is proper in this judicial district pursuant to 15 U.S.C. §§15(a) and 22 and 28 U.S.C §1391(b), (c) and (d) because during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the affected interstate trade and commerce described below has been carried out in this District. Venue is also proper in this District because the federal grand jury investigating the pricing of generic drugs is empanelled here and therefore it is likely that acts in furtherance of the alleged conspiracy took place here, where Lannett and Mylan are headquartered and where Impax's generics division, Global Pharmaceuticals ("Global"), is located.

20. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) sold digoxin throughout the United States, including in this District; (c) had substantial contacts with the United States, including in this District; and/or (d) was engaged in an illegal scheme and price-fixing conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

PLAINTIFF

21. Plaintiff, PFTHW, is a voluntary employee benefits plan organized pursuant to § 501(c) of the Internal Revenue Code for the purpose of providing health benefits to eligible participants and beneficiaries. PFTHW maintains its principal place of business in Philadelphia, Pennsylvania. PFTHW provides health benefits, including prescription drug benefits, to approximately 20,000 active participants, and their spouses and dependents. During the Class Period, PFTHW has been billed for and paid charges for drugs. As a result of the alleged conspiracy, Plaintiff was injured in its business or property by reason of the violations of law alleged herein.

DEFENDANTS

22. Lannett is a Delaware corporation that has its principal place of business in Philadelphia, Pennsylvania. Lannett is a distributor of generic digoxin and generic doxycycline. During the Class Period, Lannett sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

23. Impax is a Delaware corporation that has its principal place of business in Hayward, California. As noted above, Impax's generics division is called Global Pharmaceuticals ("Global") and is a manufacturer and distributor of generic digoxin. During the Class Period, Global sold generic digoxin to customers in this District and other locations in the United States.

24. Par is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. In January 2014, Par announced that it had entered into an exclusive United States supply and distribution agreement with Covis Pharma S.à.r.l. ("Covis") to distribute the authorized generic version of Covis' Lanoxin® (digoxin) tablets. At that time, Par began selling and shipping 0.125 mg and 0.250 mg strengths of

digoxin tablets in this country. Par also manufactures generic doxycycline. During the Class Period, Par sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

25. West-Ward is a Delaware corporation with its principal place of business in Eatontown, New Jersey. West-Ward is the United States agent and subsidiary of Hikma Pharmaceuticals PLC ("Hikma"), a London-based global pharmaceutical company and is a manufacturer and distributor of generic digoxin. During the Class Period, West-Ward sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

26. Allergan is an Irish corporation that has its global headquarters in Dublin, Ireland and its administrative headquarters in Parsippany-Troy Hills, New Jersey. During the Class Period, Allergan sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

27. Mylan is a Delaware corporation with its principal place of business in Canonsburg, Pennsylvania. During the Class Period, Mylan sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

28. Whenever in this Complaint reference is made to any act, deed or transaction of any corporation, the allegation means that the corporation engaged in the act, deed or transaction by or through its officers, directors, agents, employees or representatives while they were actively engaged in the management, direction, control or transaction of the corporation's business or affairs.

29. All acts alleged in this Complaint to have been done by Defendants were performed by their officers, directors, agents, employees or representatives while engaged

in the management, direction, control or transaction of Defendants' business affairs.

CO-CONSPIRATORS

30. Various other persons, firms, corporations and entities have participated as unnamed co-conspirators with Defendants in the violations and conspiracy alleged herein. In order to engage in the offenses charged and violations alleged herein, these co-conspirators have performed acts and made statements in furtherance of the antitrust violations and conspiracies alleged herein.

31. At all relevant times, each Defendant was an agent of each of the remaining Defendants, and in doing the acts alleged herein, was acting within the course and scope of such agency. Each Defendant ratified and/or authorized the wrongful acts of each of the Defendants. Defendants, and each of them, are individually sued as participants and as aiders and abettors in the improper acts and transactions that are the subject of this action.

INTERSTATE TRADE AND COMMERCE

32. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

33. During the Class Period, Defendants sold substantial quantities of generic digoxin and/or generic doxycycline in a continuous and uninterrupted flow of interstate commerce to customers throughout the United States.

FACTUAL ALLEGATIONS

The Industry

34. Defendants manufacture and sell, *inter alia*, generic versions of branded drugs once the patent on the branded drug expires.

35. According to the FDA's Glossary, a generic drug is "the same as a brand

name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use."[11] Once the FDA approves a generic drug as "therapeutically equivalent" to a brand drug, the generic version "can be expected to have equal effect and no difference when substituted for the brand name product." *Id.* According to a PowerPoint presentation given by Lannett at the 2014 Bank of America/Merrill Lynch Healthcare Conference, the cost of generics is "[o]ften 80-85% less than the brand."

36. Due to the price differentials between branded and generic drugs, as well as other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the branded drug. Since passage of the Hatch-Waxman Act (Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§68b-68c, 70b; 21 U.S.C. §§301 note, 355, 360cc; 28 U.S.C. §2201; 35 U.S.C. §§156, 271, 282)), every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

Market for Generic Digoxin

37. The market for generic digoxin is mature and the Defendants in that market can only gain market share by competing on price.

38. Lanoxin® is a branded version of digoxin. It was formerly a registered trademark of GlaxoSmithKline ("GSK"), which in December of 2011 sold its commercial rights in Lanoxin to Covis. Currently, Lanoxin® is manufactured by DSM Pharmaceuticals, Inc. and distributed by Covis. As noted above, in January of 2014, Par

[11] http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G.

contracted with Covis for distribution rights for an authorized generic version of Lanoxin® in the United States.

39. According to the 2015 edition of the FDA's Orange Book, the 0.250 mg strength of Lanoxin® is a reference listed drug ("RLD"). An RLD is an "approved drug product to which new generic versions are compared to show that they are bioequivalent," that is, the generic version "performs in the same manner as the Reference Listed Drug." FDA's Glossary, available at

http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#RLD.

A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA)." *Id.* Once the FDA determines that a drug company's application contains sufficient scientific evidence establishing the bioequivalence of the product to the RLD, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public. *Id.*

40. Furthermore, the FDA will generally assign a Therapeutic Equivalence Code ("TE Code") of AB to those products it finds to be bioequivalent.[12] This coding system allows users to quickly determine important information about the drug product in question.[13] For example, the FDA states that "[p]roducts generally will be coded AB if a study is submitted demonstrating bioequivalence. Even though drug products of distributors and/or repackagers are not included in the List, they are considered

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12 http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071713.htm.

13 http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#TEC.

therapeutically equivalent to the application holder's drug product if the application holder's drug product is rated AB."[14]

41. Lanoxin® in tablet form has TE Code of "AB." As the FDA has listed in its Orange Book with regard to Therapeutic Equivalents for Lanoxin®, current generic equivalents which share the code AB are those distributed by Lannett; Global, a division of Impax; West- Ward; Par; Mylan; and Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), which is a subsidiary of Sun Pharmaceutical Industries, Ltd., an Indian company. As noted above, on February 12, 2012, the FDA sent a warning letter to West-Ward over managing and testing issues that caused its generic digoxin tablets to fail to be in compliance with current good manufacturing practices as defined in 21 C.F.R. Parts 210-11.[15] West-Ward closed its New Jersey facility in November of 2012 after FDA inspectors found other problems and reopened it in July of 2013 after Hikma spent $39 million on remediation.

42. According to its Form 10-K filed with the United States Securities & Exchange Commission ("SEC") on August 27, 2015,[16] Lannett has been involved in the business of generic digoxin distribution since at least March of 2004. In March 2004, Lannett entered into a supply agreement with Jerome Stevens Pharmaceuticals ("JSP") for the exclusive distribution rights in the United States to generic digoxin and two other drugs manufactured by JSP. As reflected in the aforementioned Form 10-K, this agreement was made in exchange for four million shares of Lannett's common stock. Lannett and JSP thereafter amended the original agreement to extend the initial contract for five more years

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[14] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071713.htm.

[15] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm291643.htm.

[16] http://www.sec.gov/Archives/edgar/data/57725/000110465915062047/a15-13005_110k.htm.

(until March of 2019). As further reflected in the aforementioned Form 10-K, for additional consideration, Lannett issued to JSP 1.5 million shares of Lannett common stock, valued at approximately $20.1 million.

43. Lannett markets and distributes two potencies of generic digoxin: 0.125 mg and 0.250 mg. They both have a TE Code of AB and therefore are generic equivalents to the corresponding respective strengths of Lanoxin®. As reflected in SEC Form 10-Ks from 2007-14, Lannett's sales of generic digoxin totaled $12.4 million in 2011; $10.9 million in 2012; $11.7 million in 2013; and $54.7 million in the 2014 fiscal year.

44. By October 2013, the generic digoxin market was essentially a duopoly controlled by Lannett and Impax. Defendant West-Ward was also a competitor, but it had to suspend operations in November of 2012 in the wake of an investigation by the FDA into production problems at its manufacturing facility. It resumed participation in the generic digoxin market in July 2013 after Hikma spent $39 million in remediation efforts.

Market for Generic Doxycycline

45. The market for generic doxycycline is mature and the Defendants in that market can only gain market share by competing on price.

46. The primary actors in that market are Allergan, Lannett, Par, West-Ward and Mylan, which collectively control a commanding market share.

47. As with generic digoxin, generic doxycycline halclate in capsule form almost universally has a TE Code of AB and the RLD is Pfizer's Vibramycin®. Doxycyline monohydrate in capsule or tablet form also almost universally has a TE Code and its RLD is listed as a generic form of the drug.

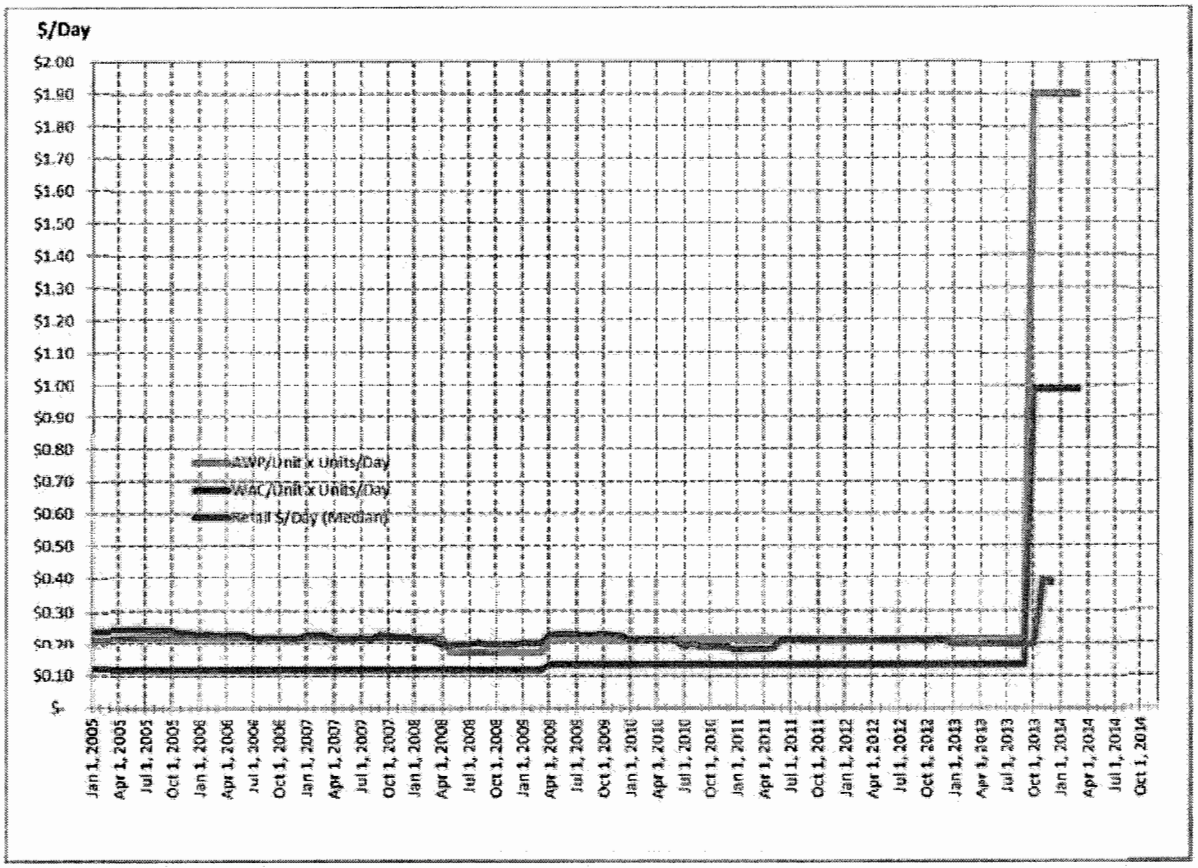
48. Total United States retail sales of doxycycline in 2013 were estimated to be

over $972 million.[17]

Defendants' Pricing Conduct For Generic Digoxin And The Effects Thereof

49. Generic digoxin pricing was remarkably stable until approximately mid-October of 2013. That stability is reflected in the following chart submitted by Dr. Stephen Schondelmeyer ("Schondelmeyer"), Director of the PRIME Institute at the College of Pharmacy for the University of Minnesota, as part of his testimony at the Senate Hearing.[18]

Figure 12. Digoxin 0.25 mg Tablet (Lannett) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)



The terms "AWP" and "WAC" in this chart refer, respectively, to "Average Wholesale Price" and "Wholesale Acquisition Price." Both prices are referred to by Schondelmeyer

[17] http://www.drugs.com/stats/doxycycline.

[18] That testimony is available at http://www.help.senate.gov/imo/media/doc/Schondelmeyer.pdf.

as benchmark prices.[19]

50. This chart reflects only a portion of the price hikes for generic digoxin that occurred. The October Letters referenced above note that prices for generic digoxin increased dramatically between October 2012 and June 2014 for the market as a whole:

Drug	SKU	Average Market Price, October 2012	Average Market Price, June 2014	Cost Increase	Average Percentage Increase
Digoxin	125mcg tablet	$.11	$1.06	$0.95	839%
Digoxin	250mcg tablet	$.11	$1.10	$0.99	884%

51. These astounding price increases were caused by sudden and abrupt pricing changes made by Lannett, West-Ward, and Impax that were followed by Par and Mylan when it entered the market in 2014 and 2015, respectively. In or about November and December 2013, pricing for .125 mg and .250 mg tablets of digoxin increased more than 750%, from $.11 and $.12 per tablet to $.91 and $1.01 per tablet. Between December 2013 and January 2014, the prices of digoxin jumped again to $1.08 and $1.11 per tablet. Daily heart medication that cost 11 or 12 cents per pill in early November 2013, cost nearly ten times more by early January 2014.

52. Data from the National Average Drug Acquisition Cost ("NADAC") on generic digoxin show price increases that led to identical prices for Lannett's, West-Ward's and Impax's generic digoxin products. The same was true of Par's pricing of generic digoxin in the United States beginning in early 2014 and of Mylan's pricing of generic digoxin when it entered the market in 2015. The following chart shows Lannett's, West-Ward's, Impax's Par's and Mylan's pricing of the 0.125 mg tablet dosage of generic digoxin during the period from October 2012 to April 2015.

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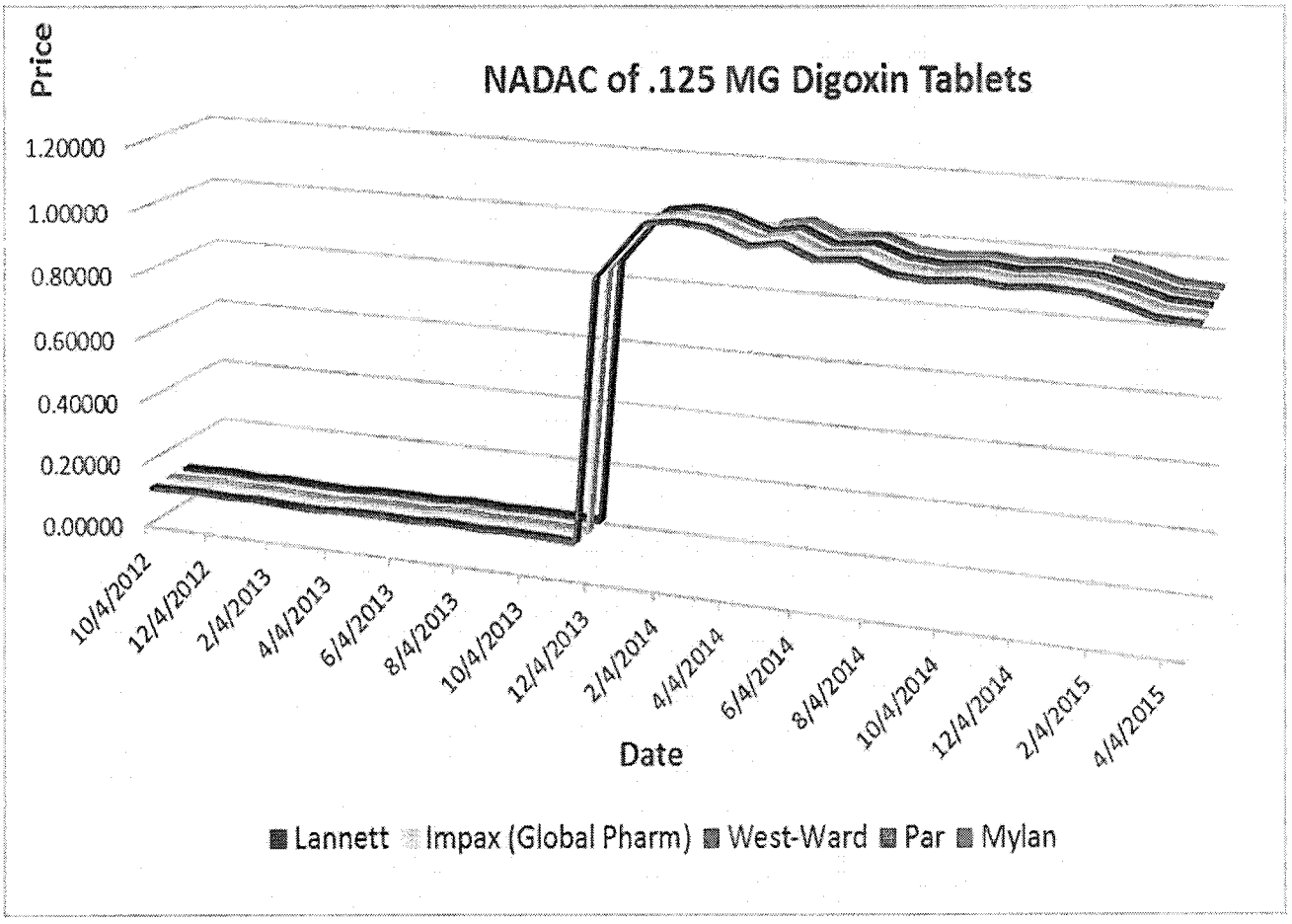
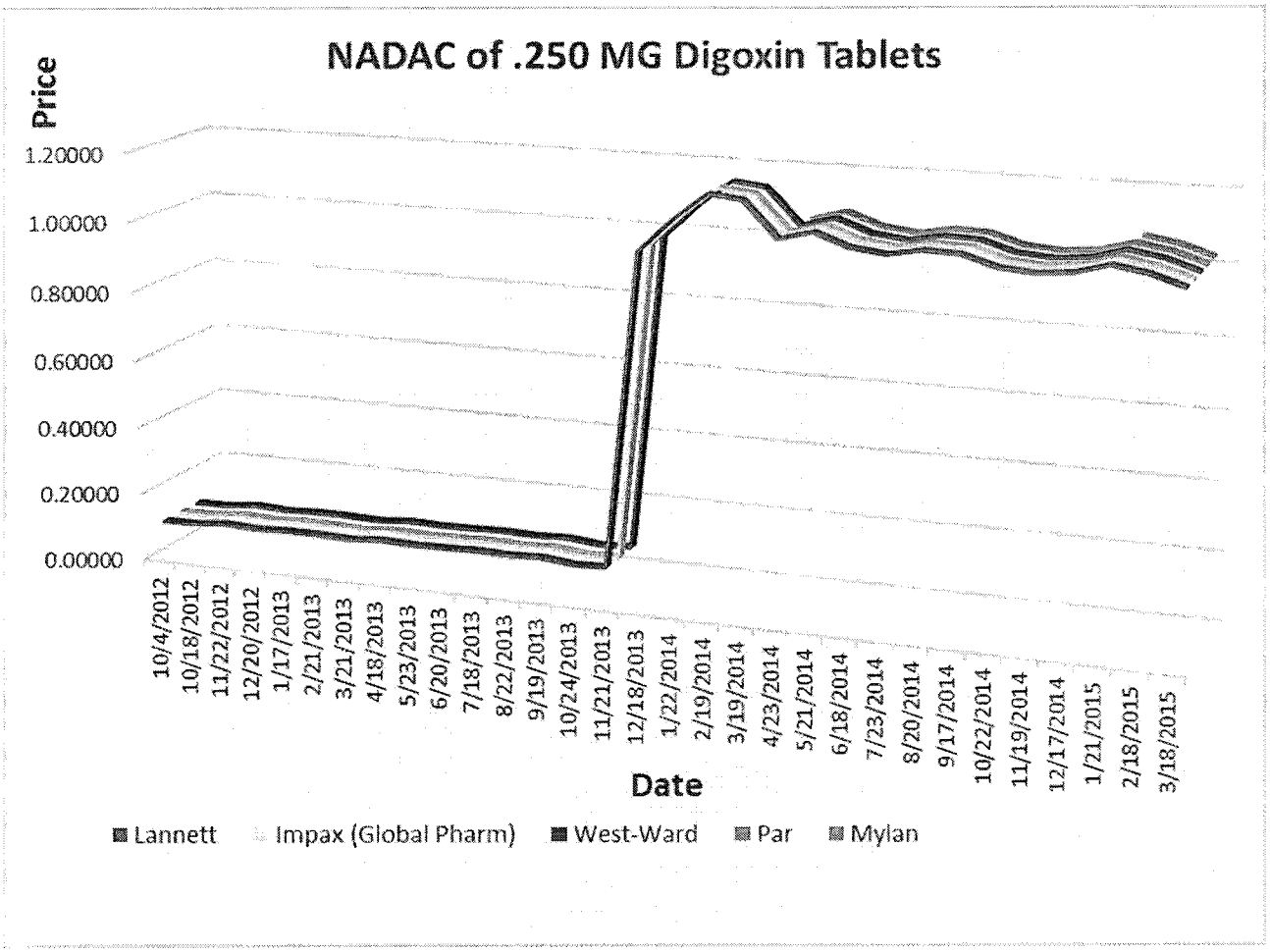
[19] *Id.* at 15.



53. The following chart, based on NADAC data, shows Lannett's, West-Ward's, Impax's Par's and Mylan's pricing of the 0.125 mg tablet dosage of generic digoxin during the period from October 2012 to mid-March 2015.



54. There were no reasonable justifications for this abrupt shift in pricing conduct.

55. Federal law requires drug manufacturers to report potential drug shortages to the FDA, the reasons therefor, and the expected duration of the shortage.[20] No supply disruption was reported by the relevant Defendants with respect to digoxin in the fall of 2013. As stated at the website of the Generics and Biosimilars Initiative on August 29, 2014, "[a]t the time of the price increases, the US Food and Drug Administration had reported no drug shortages, there was no new patent or new formulation and digoxin is not

[20] *See* http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q.

difficult to make. The companies have not yet provided an explanation for the price rise."[21] No explanation was presented at the Senate Hearing; as noted above, executives from Lannett, Impax and Par refused to testify.

56. The presence or absence of competitors in the marketplace also does not explain the price of generic digoxin. From October 2012 to around November 21, 2013, the NADAC of generic digoxin was consistently around $0.11 for the 0.125 mg tablets and between $0.11 and $0.12 for the 0.250 mg tablets. The chart presented by Schondelmeyer confirms this. This was the case even though for a portion of that period after West-Ward suspended production, Lannett and Impax were the only significant players in the market. West-Ward returned to the market in July 2013, but pricing still remained stabilized for several months. Indeed, throughout 2012 and through September 2013, as Schondelmeyer's chart shows, the price of generic digoxin remained steady. Following the astronomical price increases in the fall of 2013, Par entered the market in early 2015 and Mylan entered the market in 2015. Prices did not fall despite the *addition* of new competitors. Pricing has remained inflated to this day.

57. This abrupt shift in the pricing of generic digoxin has had a catastrophic effect on consumers. Alan Katz ("Katz"), a *Bloomberg* reporter, wrote a December 12, 2013, article titled "Surprise! Generic-Drug Prices Spike" and reported:

> Bill Drilling, an owner of a pharmacy in Sioux City, Iowa, apologizes as he rings up a customer's three-month supply of the heart medicine digoxin. The total is $113.12 — almost 10 times the cost for the same prescription in August. Digoxin isn't a new miracle drug . . . . "I've been doing this since 1985, and the only direction that generics - drug prices have gone is down," Drilling says.
>
> ***
>
> "This is starting to create hardship," he says. Many of his customers fall

[21] http://www.gabionline.net/Generics/General/Lawyers-look-at-new-price-hike-for-old-drug.

> into what is known as the Medicare "doughnut hole," a coverage gap in which patients pay 47.5 percent of branded-drug costs and 79 percent of a generic's price. Russ Clifford, a retired music teacher, learned digoxin's cost had jumped more than fourfold when he picked up his 30-day supply in mid-November. Clifford and his wife have had to dip into savings to pay their rising pharmaceutical bills.[22]

58. As further noted in the October Letters:

> This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients." (Footnotes omitted).

59. Independent pharmacist Robert Frankil ("Frankil") illustrated the hardship caused by the digoxin price increases with this anecdote offered at the Senate Hearing:

> A recent example from my own experience is the price of Digoxin — a drug used to treat heart failure. The price of this medication jumped from about $15 for 90 days' supply, to about $120 for 90 days' supply. That's an increase of 800%. One of my patients had to pay for this drug when he was in the Medicare Part D coverage gap in 2014. Last year, when in the coverage gap he paid the old price. This year he paid the new price. Needless to say, the patient was astounded, and thought I was overcharging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the federal government).[23]

Defendants' Pricing Conduct For Generic Doxycycline And The Effects Thereof

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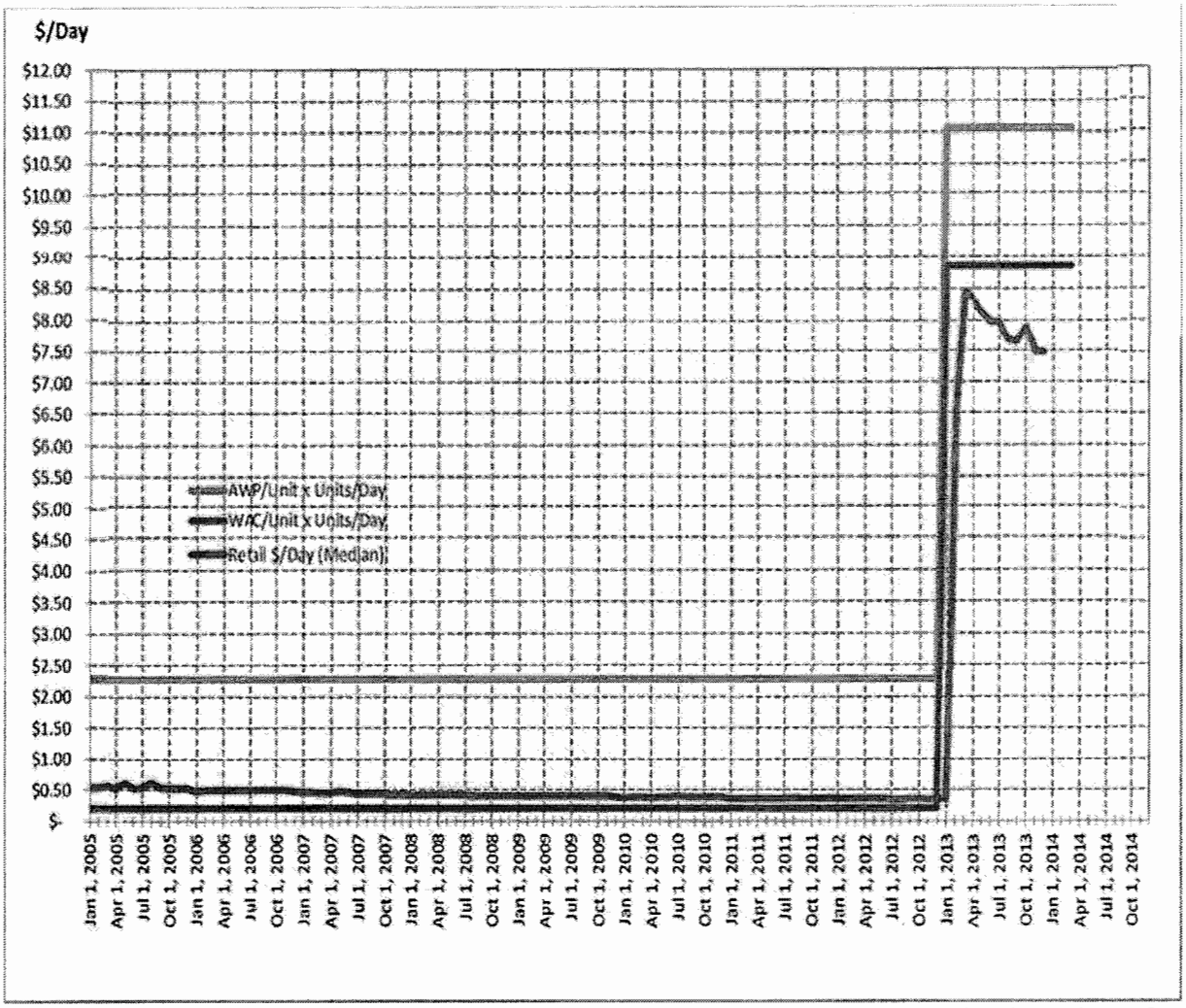
[22] *See* http://www.bloomberg.com/bw/articles/2013-12-12/generic-drug-prices-spike-in- pharmaceutical-market-surprise.

[23] http://www.help.senate.gov/imo/media/doc/Frankil.pdf.

60. For generic doxycycline, the pattern of huge price increases started in the fall of 2012, a year earlier than for generic digoxin.

61. Schondelmeyer, in his testimony at the Senate Hearing, presented the following chart showing the sudden increase in West-Ward's pricing for generic doxycycline the AWP of which went from under $2.50 for a day of therapy for 100mg capsules of doxycycline hyclate to over $11 by January 2013:

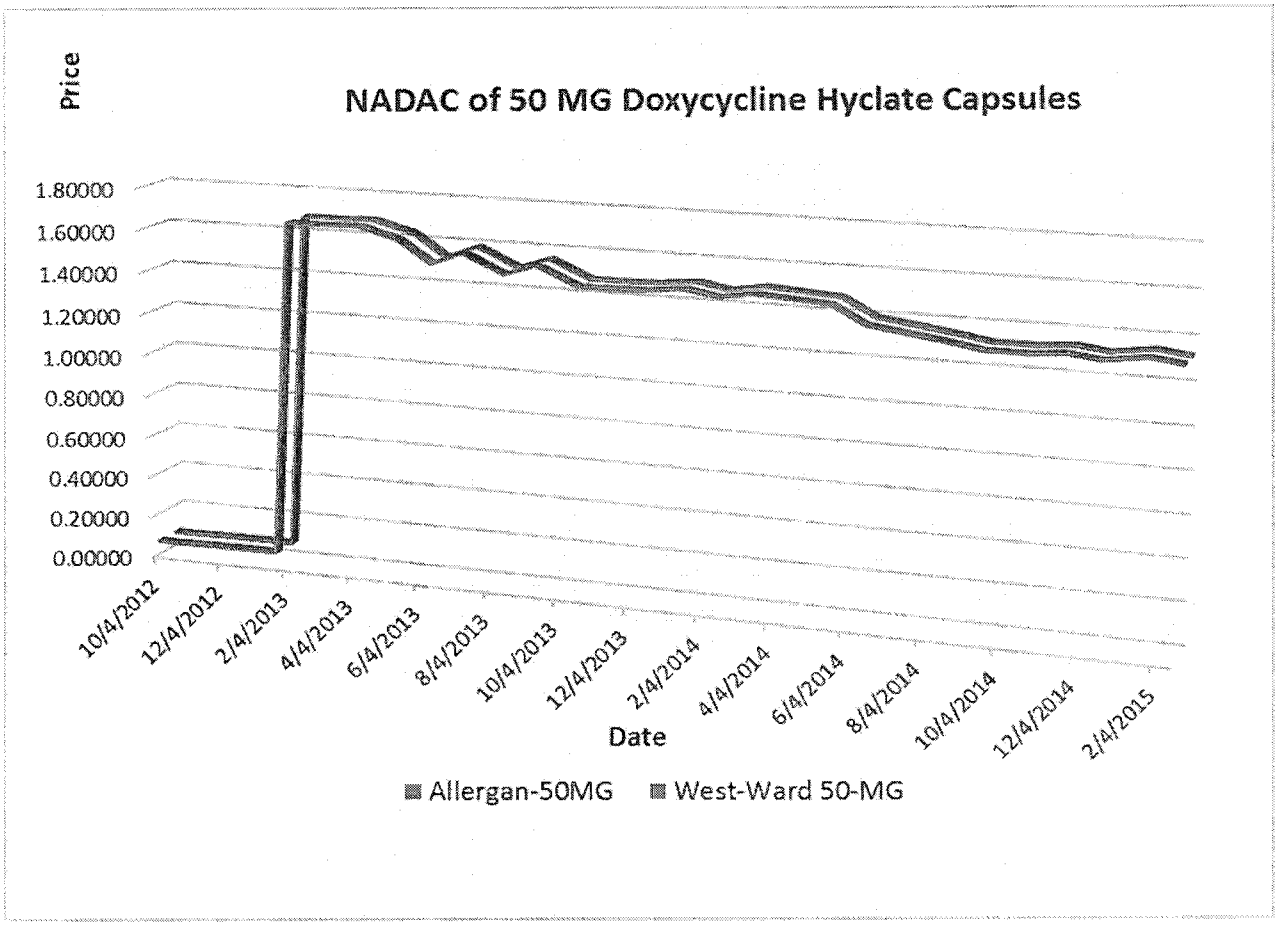


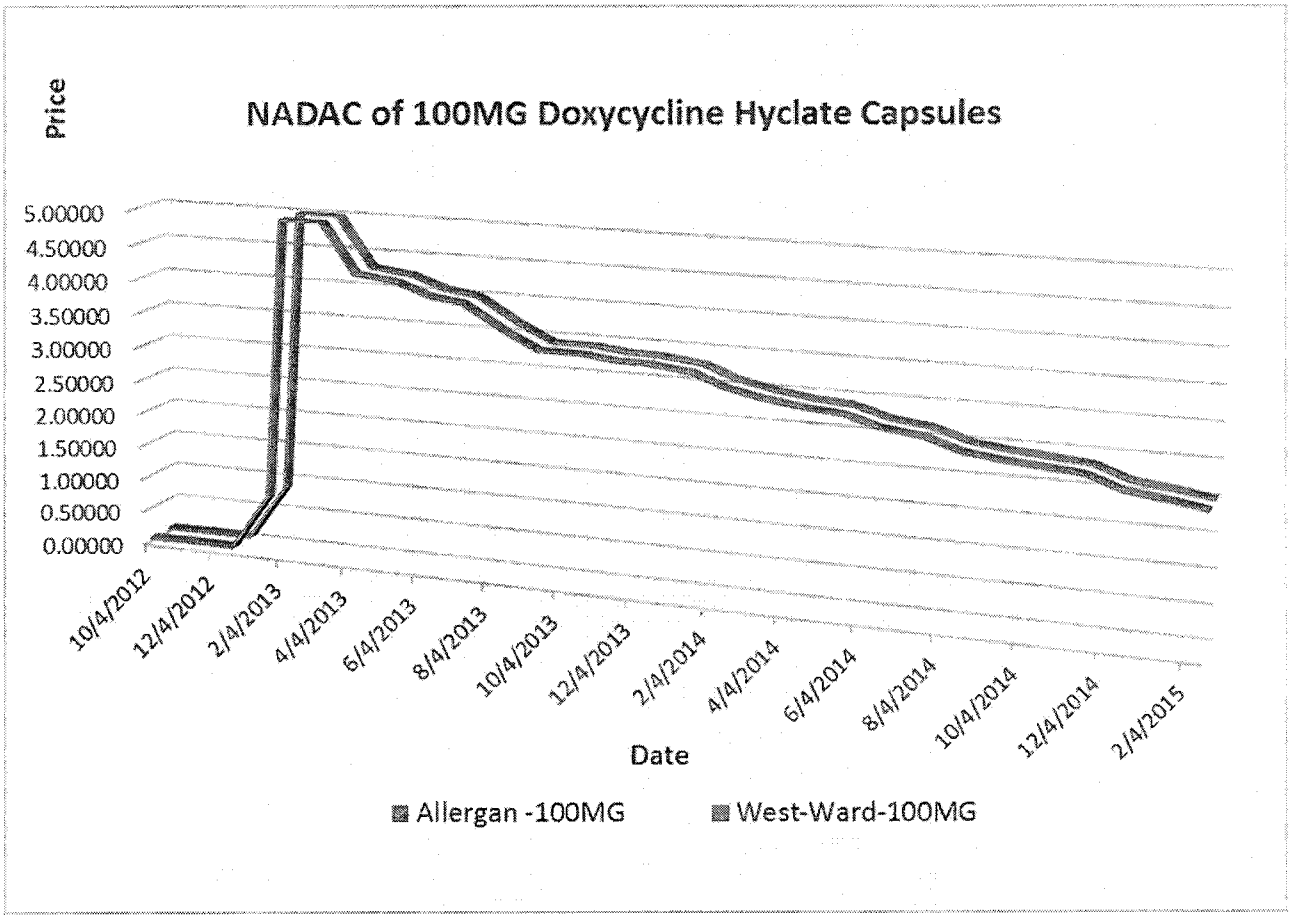
62. Similarly, Sanders and Cummings noted huge increases in the price of

generic doxycycline in their October Letters:

Drug	SKU	Average Market Price October 2013	Average Market Price April 2014	Cost Increase	Average Percentage Increase
Doxycycline Hyclate	bottle of 50, 100mg capsules	$4	$191	$187	5,025%
Doxycycline Hyclate	bottle of 50, 100mg tablets	$3	$191	$187	4,986%
Doxycycline Hyclate	bottle of 50, 50mg capsules	$3	$70	$67	2,191%
Doxycycline Hyclate	bottle of 500, 100mg capsules	$27	$1,849	$1,822	7,105%
Doxycycline Hyclate	bottle of 500, 100mg tablets	$20	$1,849	$1,829	8,281%

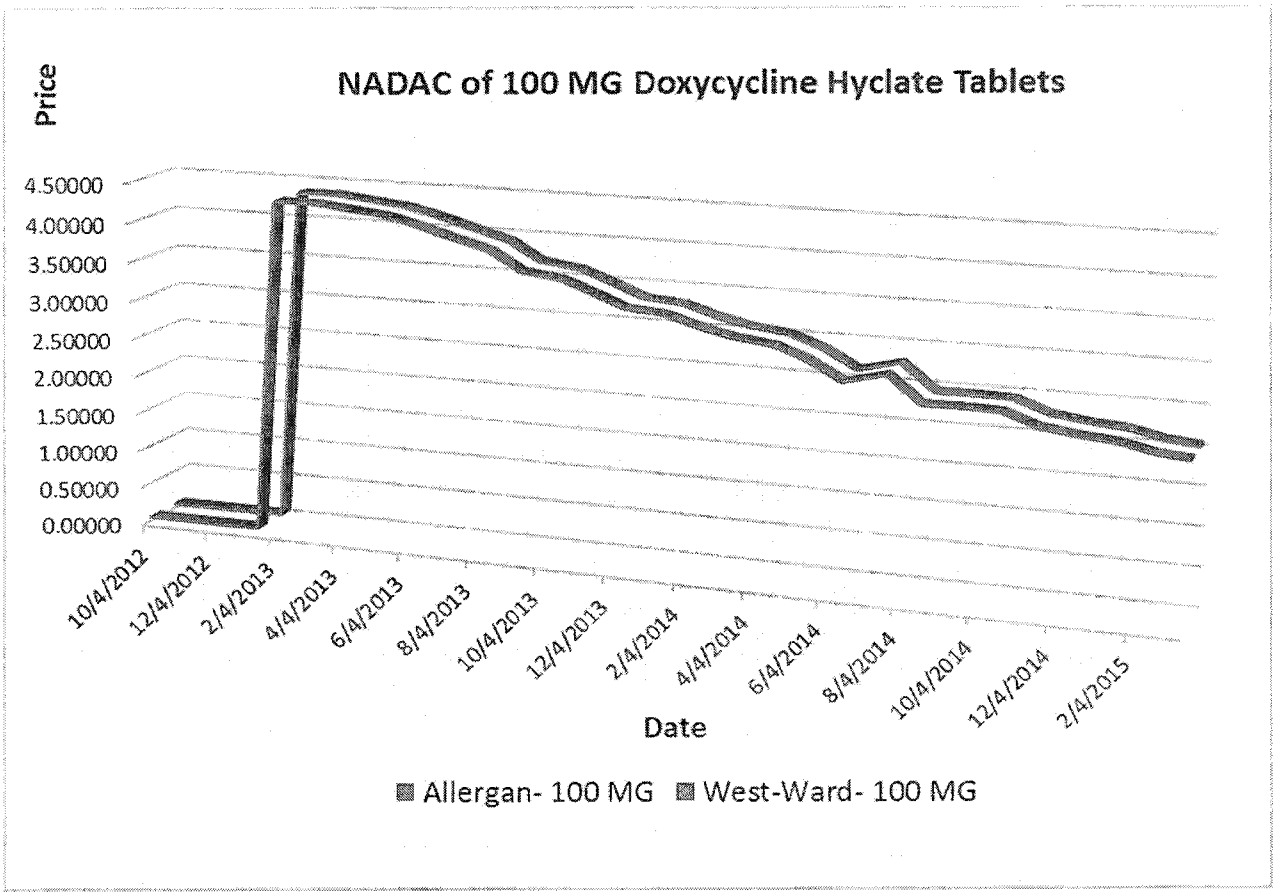
63. The NADAC data for 50 mg and 100 mg of generic doxycycline hyclate capsules manufactured by Defendants Allergan and West-Ward reveals a similar pattern:





64. Although there was some decline in prices for both dosages of doxycycline hyclate capsules, prices did not decline to the levels that existed prior to December of 2012 in this period.

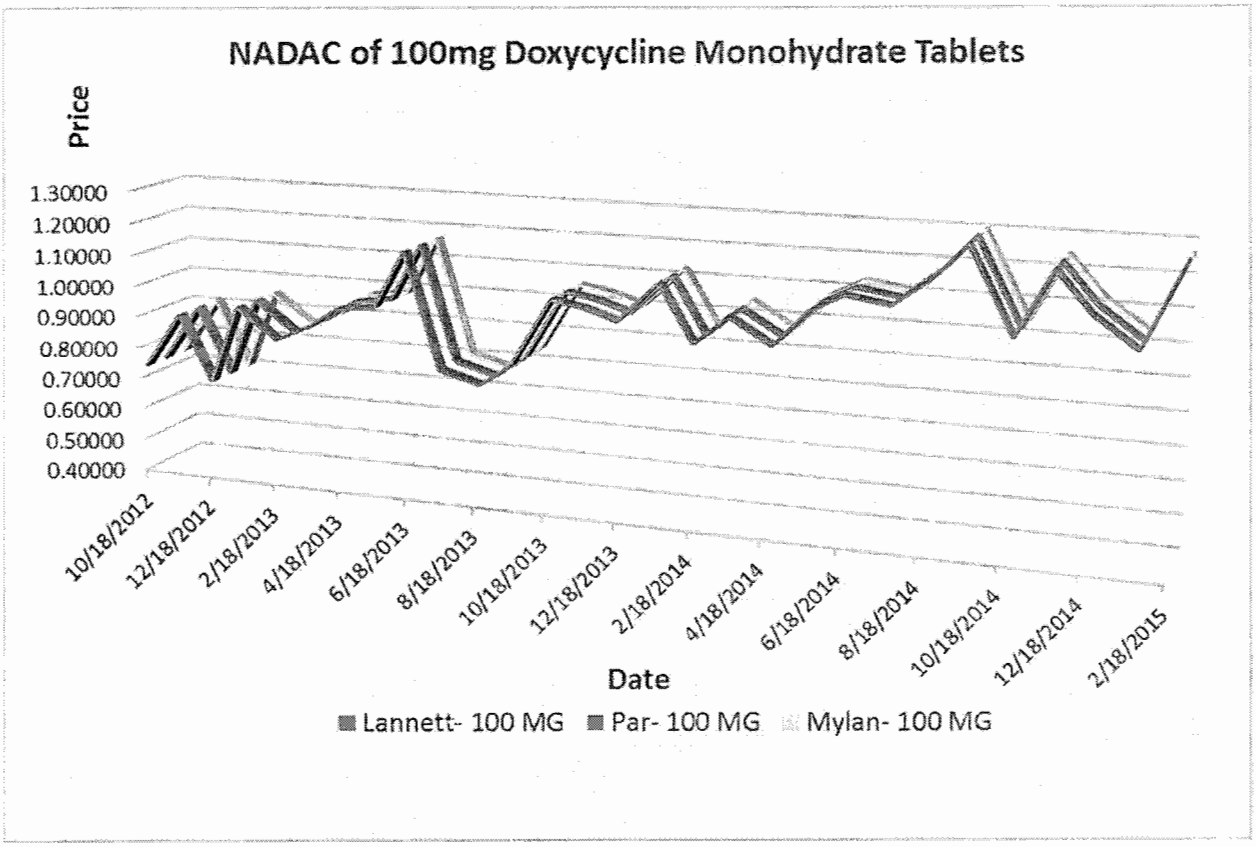
65. The NADAC data for 100mg of generic doxycycline hyclate tablets manufactured by Allergan and West-Ward likewise illustrates a similar pattern:



There were no reasonable justifications for this abrupt shift in pricing conduct. The FDA did announce that a shortage of doxycycline in January of 2013; but that generic drug was placed on the resolved shortage list in October of 2013.[24]

[24] *See* http://www.cdc.gov/std/treatment/doxycyclineShortage.htm.

66. The NADAC data for 100mg doxycycline monohydrate tablets manufactured by Lannett, Par and Mylan during the period from October of 2012 through mid-February of 2015 is depicted in the following chart; while prices for this dosage reflect more of a saw tooth pattern, again, it is one of a substantial increasing trend.



67. These price hikes caused extreme hardship to consumers. As reported on WSMV- TV of Nashville's website in March 2013:

> Many people may not recognize the name, but they have probably used it for a health problem at one point.
>
> Doctors use doxycycline to treat a wide range of issues, including everything from acne to Lyme disease, anthrax exposure and even heartworm in our pets.
>
> However, the once cheap and effective drug has now dramatically gone up in price, and that has health professionals concerned.

> Hospitals like Vanderbilt University Medical Center keep doxycycline in stock, but some folks worry the cure for their ailment could now be financially out of reach.
>
> "It's a change that occurred overnight," said Vanderbilt pharmacy manager Michael O'Neil.
>
> Not long ago, the pharmacy at Vanderbilt's hospital could purchase a 50-count bottle of 100 mg doxycycline tablets for $10, but now the same bottle costs a staggering $250.
>
> "That's concerning to us, both as citizens and practitioners, when you see a huge increase like this in a price of a drug," O'Neil said.
>
> Vanderbilt keeps thousands of doxycycline pills on hand in the event of a bioterrorist attack, like anthrax, and O'Neil said replacing expired pills is prohibitive.
>
> "This one is just hurting us when we need to replace the medication," he said.
>
> But it's the most vulnerable who are in the most jeopardy. For a pet, a heartworm diagnosis can be a death sentence without doxycycline.
>
> Veterinarian Dr. Joshua Vaughn of the Columbia Hospital for Animals is already seeing the tragic results.
>
> "We had one patient who we diagnosed with heartworm. We recommended heartworm treatment, but when they saw the total dollar amount, they elected not to treat the dog at all,: Vaughn said.
>
> While manufacturers say they are having problems with raw supply, many in the medical community see greed as an overriding factor.
>
> Vaughn said he wrote a recent prescription for doxycycline that cost $77. This week, the price increased to nearly $3,000.[25]

Lannett's Statements About Generic Drug Competition

68. Defendants' sudden and massive price increases represented a sharp departure from the previous years of low and stable prices. This in itself is indicative of

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[25] http://www.wsmv.com/story/21616095/sudden-increase-in-cost-of-common-drug-concerns-many.

collusion. In addition, Defendant Lannett's own statements – in documents and in oral remarks by Bedrosian of Lannett at quarterly earnings calls with market analysts and the investigations of state and federal antitrust regulators - reinforce this inference of collusion.[26]

69. In a fourth quarter 2013 earnings call that occurred on September 10, 2013, Bedrosian signaled Lannett's intention to increase prices and his expectations that his competitors would follow suit. Discussing the role of Smith, one of the persons apparently subpoenaed by DOJ, Bedrosian said:

> We're not a price follower. We tend to be a price leader on price increasing and the credit goes to my sales vice president. He takes an aggressive stance towards raising prices. He understands one of his goals, his objectives as a sales vice president is to increase profit margins for the company. And he's the first step in that process.... ***I am finding a climate out there has been changed dramatically and I see more price increases coming from our competing—competitors than I've seen in the past. And we're going to continue to lead. We have more price increases planned for this year within our budget. And hopefully, our competitors follow suit.*** (Emphases added).

70. In a subsequent earnings call, Bedrosian reported that Lannett's chief competitor had indeed heeded its price increase signal. In a first quarter 2014 earnings call on November 7, 2013 -- after the initial generic digoxin price increases -- Bedrosian noted, referring to Impax, that ***"[w]e've had a recent price increase on the [generic digoxin] product as well because we are now only 1 of 2 people in the market. And as a result, I expect that product to do very well.***" (Emphases added).

71. The very next quarter, Bedrosian expressed complacency about the entry of a new competitor in the form of Par. On February 6, 2014 – after more price increases on

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[26] http://seekingalpha.com/symbol/LCI?source=search_general&s=lci.

generic digoxin had occurred and after Par had entered the market -- Bedrosian said he was not concerned about this new entry: "[a]nd we see Par as one of our rational competitors in the marketplace." As he went on to note, "we're not troubled by their pricing in the marketplace. Not at all."

72. In some quarterly earnings call held on November 3, 2014, Bedrosian again expressed confidence that Lannett would not have to engage in price competition generally in the generic drug market. He said Lannett and its competitors were "***less concerned about grabbing market share. We're all interested in making a profit, not how many units we sell***." (Emphases added). Bedrosian went on to discuss, *inter alia*, Par and Impax, saying "***the companies we're looking at here are not irrational players. I don't see them just going out and trying to grab market share.***" (Emphases added). He also noted that Mylan was expected to enter the market, "but Mylan is one of those ***rational competitors, so we're not really expecting anything crazy from them***." (Emphases added). He predicted that price increases would continue.

73. On February 4, 2015, in another quarterly earnings call, Bedrosian confirmed there would be a moratorium on price competition. He stated: "***I think you're going to find more capital pricing [in the generic marketplace], more - I'll say less competition, in a sense. You won't have price wars***." (Emphases added). In his view, "***I just don't see the prices eroding like they did in the past***." (Emphases added).

74. Thus, for Lannett, irrational competitors were those who competed on price in order to obtain market share. It understood that Impax, Par and Mylan, among others, were no longer interested in doing that, an understanding that could only exist if the three firms had reached a consensus on how to price. Bedrosian's predictions bespeak that

consensus. Bedrosian was also certain of reaching the same consensus with Mylan.

75. Frederick Wilson, the CEO of Impax, also spoke to this topic in a third quarter 2014 earnings call: "we've done what most of the other generic competitors have done, we look at opportunities, we look at how competition shifts, we look at where there may be some market movement that will allow us to take advantages on price increases and we've implemented those…."[27]

76. This meeting of the minds among the competing sellers of generic digoxin and generic doxycycline assured them handsome profits. Bedrosian noted in the February 4, 2015, earnings call that Lannett "recorded the highest net sales and net income in our company's history." Gross profits in the first six months of the 2015 fiscal year were $158.8 million or 76% of net sales, compared with $42.3 million or 37% of net sales during the previous fiscal year. Generic digoxin pricing played a big role in its success. The 2015 Lannett Presentation noted that generic digoxin accounted for 23% of the company's revenues. As noted in the same presentation, Lannett is highly dependent on price increases for revenue growth.

77. Likewise, according to its 2015 SEC Form 10-K filed on February 26, 2015, Impax experienced $596 million in total revenues in the 2014 calendar year, compared to $511 million in 2013—a 17% increase.[28] One of the primary factors in this growth was "higher sales of our Digoxin." *Id. at* 61-62.

Congressional And Regulators' Responses

78. As noted above, the unseemly profits made by the generic drug

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[27] http://www.nasdaq.com/symbol/ipxl/call-transcripts.

[28] http://d1lge852tjjqow.cloudfront.net/CIK-0001003642/c545ab21-aa3d-4426-a0b9-ba4373b6c213.pdf?noexit=true.

manufacturers led to inquiries by Congress and to the Senate Hearing, where numerous witnesses referenced the pricing history summarized above.

79. Sanders and Cummings followed up on the Senate Hearing by writing a letter on February 24, 2015, to the Office of the Inspector General ("OIG") of the Department of Health & Human Services, asking it to investigate the effect price increases of generic drugs, including generic digoxin, have had on generic drug spending within the Medicare and Medicaid programs.[29] The OIG responded in a letter dated April 13, 2015, saying it planned to engage in a review of quarterly average manufacturer prices for the 200 top generic drugs from 2005 through 2014.[30]

80. In July of 2014, George Jepsen, the Connecticut AG, issued subpoenas to each of the Defendants, specifically saying that there was "reason to believe" that a conspiracy took place "which is for the purpose, or has the effect of, (a) fixing, controlling or maintaining prices, rates, quotations, or fees; or (b) allocating or dividing customers or territories…." This subpoena is thus not a "fishing expedition"; it is very exact, as reflected in Appendix A.

81. Commencing in November 2014, the DOJ issued grand jury subpoenas to Lannett, Impax, Par, Allergan, and Mylan and, in some cases, their employees. These subpoenas have been acknowledged in SEC filings by all three companies. (It is not publicly known if West-Ward also received a subpoena, because its foreign parent, Hikma, does not make disclosures to the SEC).

82. In an SEC Form 10-Q dated February 6, 2015, Lannett has said that on

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[29] http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.
[30] http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

November 3, 2014, "the Senior Vice-President of Sales and Marketing was served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act."[31] The responses to that subpoena led to the issuance of a second grand jury subpoena to Lannett itself. It noted in the same SEC filing that on December 5, 2014, "[t]he Company was served with a grand jury subpoena related to the federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoena requests corporate documents from the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale, or pricing of certain products." A report in *Pharmacy Times* described the subpoenas as follows:

> The Lannett Company, Inc., subpoena covers 2 specific areas related to antitrust laws and generic drug pricing. The first portion covers a Connecticut Attorney General investigation into whether the company or its employees engaged in price fixing, maintaining, or controlling for digoxin. The second portion serves the company's senior vice president of sales and marketing with a grand jury subpoena pertaining to Sherman antitrust act violations in the generic drug industry. That subpoena requests any documents exchanged with competitors related to the sale of any generic prescription medications during any time period.[32]

Similar statements are contained in Lannett's most recent SEC Form 10-Q, filed on February 9, 2016.[33]

83. On August 27, 2015, Lannett issued a new SEC Form 10-K. It contains this further explanation of the DOJ investigation:

In fiscal year 2015, the Company and certain affiliated individuals each

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[31] http://app.quotemedia.com/data/downloadFiling?webmasterId=101533&ref=10044800&type=HTML&symbol=LCI&companyName=Lannett+Co.+Inc.&formType=10-Q&dateFiled=2015-02- 06.

[32] http://www.pharmacytimes.com/publications/issue/2014/December2014/Senate-Hearing- Investigates-Generic-Drug-Prices.

[33] http://www.sec.gov/Archives/edgar/data/57725/000110465916094983/a15-24119_110q.htm.

> were served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoenas request corporate documents of the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale, or pricing of certain products, generally for the period of 2005 through the dates of the subpoenas.[34]

Similar statements are contained in Lannett's most recent Form 10-Q, referenced above. Thus, Lannett has now indicated that the DOJ has caused subpoenas to be issued to a number of "affiliated individuals" and that the scope of the investigation extends back a decade.

84. Similarly, in an SEC Form 10-K dated March 12, 2015, Par stated that "[o]n December 5, 2014, we received a subpoena from the Antitrust Division of the DOJ requesting documents related to communications with competitors regarding our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets."[35] Par repeated this disclosure in its Form 10-Qs issued for the second quarter of 2015.[36] In a Form 10-Q for the third quarter of 2015, Endo International plc, the parent company for Par, stated that "[o]n December 5, 2014, the Company's subsidiary, Par, received a Subpoena to Testify Before Grand Jury from the Antitrust Division of the DOJ and issued by the U.S. District Court for the Eastern District of Pennsylvania. The subpoena requests documents and information focused primarily on product and pricing information relating to Par's authorized generic version of Lanoxin (digoxin) oral tablets and Par's generic doxycycline

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[34] http://www.sec.gov/Archives/edgar/data/57725/000110465915062047/a15-13005_110k.htm.
[35] https://www.sec.gov/Archives/edgar/data/878088/000087808815000002/prx-20141231x10k.htm.
[36] This filing was formerly available at the web page that follows, but has since been withdrawn: http://pr.parpharm.com/phoenix.zhtml?c=81806&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTEwNDIwNTIxJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVElPTl9FTlRJUkUmc3Vic2lkPTU3.

products, and on communications with competitors and others regarding those products. Par is cooperating fully with the investigation."[37]

85. Impax's 2015 Form 10-K referenced above states that "[o]n November 3, 2014, a sales representative of the Company received a subpoena from the Justice Department's Antitrust Division requesting the production of documents to and testimony before the grand jury of the Eastern District of Pennsylvania. The request relates to any communication or correspondence with any competitor (or an employee of any competitor) in the sale of generic prescription medications." Subsequently, in an SEC Form 10-Q filed on May 11, 2015, Impax indicated that the "[o]n December 5, 2014, we received a subpoena from the Antitrust Division of the DOJ requesting documents related to communications with competitors regarding our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets and our generic doxycycline products."[38] This assertion was repeated in Impax's Form 10-Q filed on August 10, 2015 and reconfirmed in its Form 10-K filed on February 22, 2016.[39]

86. On August 6, 2015, Allergan filed an SEC Form 10-Q, in which it disclosed that "[o]n June 25, 2015, the Company received a subpoena from the U.S. Department of Justice ('DOJ'), Antitrust Division seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with

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[37] http://phx.corporate-ir.net/phoenix.zhtml?c=123046&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTEwNTY2NjAwJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVElPTl9FTlRJUkUmc3Vic2lkPTU3.

[38] http://d1lge852tjjqow.cloudfront.net/CIK-0001003642/88fbdd3c-25b3-4640-935d-4c2ced2a6a47.pdf?noexit=true.

[39] http://d1lge852tjjqow.cloudfront.net/CIK-0001003642/0995ec20-ce96-4de1-98aa-4aacfdb675e6.pdf?noexit=true; http://d1lge852tjjqow.cloudfront.net/CIK- 0001003642/0d396bab-0306-4c61-90fe-b5cce6e02624.pdf?noexit=true.

competitors about such products."[40] As one article noted, "[l]ike the other generic manufacturers who have been subpoenaed — Impax Laboratories, Lannett Company, and Par Pharmaceutical Companies, Inc. — Actavis has manufactured digoxin. Actavis has also supplied doxycycline, which may be significant because Par had disclosed that its DOJ subpoena sought communications related to doxycycline."[41]

87. On December 4, 2015, Mylan N.V., the parent of Defendant Mylan, issued an SEC Form 8-K that stated "[o]n December 3, 2015, a subsidiary of Mylan N.V. ... received a subpoena from the Antitrust Division of the U.S. Department of Justice ... seeking information relating to the marketing, pricing and sale of our generic Doxycycline products and any communications with competitors about such products."[42] Regulatory investigations against Mylan are not limited to doxycycline, however. In its SEC Form 10-K filed on February 16, 2016, Mylan N.V. reported that "[o]n December 21, 2015, the Company received a subpoena and interrogatories from the Connecticut Office of the Attorney General seeking information relating to the marketing, pricing and sale of certain of the Company's generic products (including Doxycycline) and communications with competitors about such products."[43]

88. The fact that these companies and/or their employees received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ's *Antitrust Division Manual.*[44] Section F.1 of that chapter notes that "staff should

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[40] https://www.sec.gov/Archives/edgar/data/1578845/000156459015006357/agn- 10q_20150630.htm.
[41] http://www.antitrustupdateblog.com/blog/doj-generic-price-fixing-investigation-targets- allergans-actavis-unit/.
[42] http://www.sec.gov/Archives/edgar/data/1623613/000119312515394875/d225442d8k.htm.
[43] http://files.shareholder.com/downloads/ABEA-2LQZGT/146191293x0xS1623613-16-46/1623613/filing.pdf.
[44] http://www.justice.gov/atr/public/divisionmanual/chapter3.pdf.

consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution." *Id. at* III-82. The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division." *Id.* "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation." *Id. at* III-83. "The investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred." *Id.* Thus, the fact that Lannett, Impax, Allergan, Mylan and Par or their employees received federal grand jury subpoenas is a strong indicator that antitrust offenses have occurred.

89. Commentators have also taken note of the criminal subpoenas being issued. As noted on one legal website:

> The Justice Department's subpoenas focus on sharing and exchanging of pricing information and other issues among generic drug companies. The initial subpoenas, including two senior executives, suggest that the Justice Department has specific information relating to their participation in potentially criminal conduct. It is rare for the Justice Department to open a criminal investigation with specific subpoenas for individuals, along with company-focused subpoenas.
>
> Given the breadth of such a potential cartel investigation, the Justice Department's inquiry of the generic pharmaceutical industry could be significant. The prices for a large number of generic drug prices have increased significantly over the last year. There does not appear to be any rational explanation for such increases involving a diverse set of products.
>
> The scope of these price increases and the timing of them certainly raise

serious concerns about collusive activity among competitors.[45]

Or, as Mark Rosman, former assistant chief of the National Criminal Enforcement Section of the DOJ's Antitrust Division noted in an article on the "unusual" nature of the criminal subpoenas, "[a] DOJ investigation into the alleged exchange of pricing information in the pharmaceutical industry likely indicates that the agency anticipates uncovering criminal antitrust conduct in the form of price-fixing or customer allocation."[46]

90. And, as another legal commentator has recently noted:

> The recent disclosure widens the DOJ's criminal probe into whether or not leading generic drug providers are colluding to artificially raise generic drug prices. According to data from the Centers for Medicare and Medicaid Services (CMS), more than half of all generic drug prices rose between June 2013 and June 2014, including 10 percent of all generic drugs doubling in price during that time. As the fourth largest generics producer in the world, at least prior to the Teva deal, Allergan is largest company to be involved in the DOJ investigation so far. The probe became public last November when Impax was served with several criminal grand jury subpoenas. Lannett announced in a regulatory filing earlier in the year that the company, as well as its senior vice-president of sales and marketing, was being served with grand jury subpoenas as well. Like Lannett, Allergan wrote that it intends to fully cooperate with the investigation. Neither the DOJ, nor the company would comment further on the investigation beyond the filings. While Allegan made no mention of the medicines involved in the suspected collusion, filings from other companies indicate that the heart drug digoxin and the antibiotic doxycycline are among those under investigation.[47]

Factors Increasing The Market's Susceptibility To Collusion

91. Publicly available data on the generic digoxin and doxycycline markets in the United States demonstrates that it is susceptible to cartelization by the Defendants. Factors that make a market susceptible to collusion include: (1) a high degree of industry concentration; (2) significant barriers to entry; (3) inelastic demand; (4) the lack of

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[45] http://www.jdsupra.com/legalnews/criminal-global-cartel-focus-on-generic-92387/.
[46] https://www.wsgr.com/publications/PDFSearch/rosman-1114.pdf.
[47] http://www.legalreader.com/doj-subpoenas-allergan-as-generics-antitrust-probe-widens/.

available substitutes for the goods involved; (5) a standardized product with a high degree of interchangeability between the goods of cartel participants; (6) absence of a competitive fringe of sellers; and (7) intercompetitor contacts and communication.

92. ***Industry Concentration***. A high degree of concentration facilitates the operation of a cartel because it makes it easier to coordinate behavior among co-conspirators.

93. In the United States generic digoxin and generic doxycycline markets, the number of competitors has dwindled, creating cartel conditions. The firms that currently control most of the market are the Defendants. A graphic available at the website of one pharmacy benefits manager ("PBM")[48] reflects this development with respect to the market for generic digoxin:

94. As the PBM goes on to explain:

Overall, a grand jury is investigating the generic pharmaceutical industry as a whole for possible violations of anti-trust laws. More specifically, in early November 2014, the U.S. Department of Justice issued subpoenas to two generic drug makers seeking

[48] https://www.optum.com/thought-leadership/whatcanbedone.html.html.